IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	C.A. No. 1:23-00152-CFC
VANDA PHARMACEUTICALS INC., Plaintiff, v. APOTEX INC. and APOTEX CORP., Defendants.	C.A. No. 1:23-00153-CFC

DEFENDANTS' OPENING BRIEF IN SUPPORT OF THEIR MOTION FOR JUDGMENT ON THE PLEADINGS

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
Nathan R. Hoeschen (No. 6232)
SHAW KELLER LLP
I.M. Pei Building
1105 N. Market Street, 12th Floor
Wilmington, DE 19801
Tel: (302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
nhoeschen@shawkeller.com

Of Counsel:

J.C. Rozendaal
Deirdre M. Wells
William H. Milliken
Byron L. Pickard
William D. Rodenberg
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 New York Avenue, NW
Washington, DC 20005
Tel: (202) 371-2660

Counsel for Defendant and Counterclaim Plaintiff Teva Pharmaceuticals USA, Inc.

Kaan Ekiner (No. 5607)
COZEN O'CONNOR
1201 N. Market Street, Suite 1001
Wilmington, DE 19801
Tel: (302) 295-2046
kekiner@cozen.com

Of Counsel:

W. Blake Coblentz
Aaron S. Lukas
Kerry B. McTigue
COZEN O'CONNOR
1200 19th Street, NW
Washington, DC 20036
Tel: (202) 912-4800

Keri L. Schaubert
COZEN O'CONNOR
3 WTC, 175 Greenwich Street, 55th Floor
New York, NY 10007
Tel: (212) 883-2258

Counsel for Defendants and Counterclaim Plaintiffs Apotex Inc. and Apotex Corp.

Dated: June 28, 2023

TABLE OF CONTENTS

I. INTRODUCTION 1

II. NATURE AND STAGE OF THE PROCEEDINGS 1

A. The Pending Actions 1

B. The Prior Litigation Involving Related Patents 2

III. SUMMARY OF THE ARGUMENT 2

IV. THE ASSERTED '129 PATENT 3

V. RELEVANT LEGAL STANDARDS 5

A. Judgment on the Pleadings 5

B. Invalidity Based on Collateral Estoppel 6

VI. ARGUMENT 8

A. Vanda is Collaterally Estopped from Asserting The '129 Patent Against Defendants 8

1. This Court Has Already Found the Operative Method Steps Claimed in the '129 Patent Obvious 9

B. In The Alternative, Defendants Are Entitled to Judgment on the Pleadings of Non-Infringement 16

C. The Court should dismiss this case with prejudice 20

VII. CONCLUSION 20

TABLE OF AUTHORITIES

Cases **Page(s)**

Ashcroft v. Iqbal,
556 U.S. 662 (2009).....6, 20

Biogen Int'l GMBH v. Amneal Pharm. LLC,
Case No. 17-823 (MN), 2020 WL 5549084 (D. Del. Sept. 16, 2020) 7-8

Blonder-Tongue Lab'ys, Inc. v. Univ. of Ill. Found.,
402 U.S. 313 (1971).....7

BotM8 LLC v. Sony Corp. of Am.,
4 F.4th 1342 (Fed. Cir. 2021) 17

Brown v. 3M,
265 F.3d 1349 (Fed. Cir. 2001) 5, 9-10, 11

In re Burlington Coat Factory Sec. Litig.,
114 F.3d 1410 (3d Cir. 1997) 6, 20

DSU Med. Corp. v. JMS Co., Ltd.,
471 F.3d 1293 (Fed. Cir. 2006) (en banc) 17

Google LLC v. Hammond Dev. Int'l, Inc.,
54 F.4th 1377 (Fed. Cir. 2022) 7

HZNP Meds. LLC v. Actavis Lab'ys UT, Inc.,
940 F.3d 680 (Fed. Cir. 2019) 18, 19, 20

Intellectual Ventures I LLC v. Capital One Fin. Corp.,
850 F.3d 1322 (Fed. Cir. 2017) 7

Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.,
458 F.3d 244 (3d. Cir. 2006) 7

In re Kao,
639 F.3d 1057 (Fed. Cir. 2011) 13

King Pharm., Inc. v. Eon Labs, Inc.,
616 F.3d 1267 (Fed. Cir. 2010) 12-13, 14

Praxair Distr., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd.,
890 F.3d 1024 (Fed. Cir. 2018). 13, 14

Miss. Chem. Corp. v. Swift Agric. Chems. Corp.,
717 F.2d 1374 (Fed. Cir. 1983) 6

Mycogen Plant Sci., Inc. v. Monsanto Co.,
252 F.3d 1306 (Fed. Cir. 2001) 7

Ohio Willow Wood Co. v. Alps South, LLC,
735 F.3d 1333 (Fed. Cir. 2013) 6-7, 11

Rodriguez v. Stevenson,
243 F. Supp. 2d 58 (D. Del. 2002)..... 5-6

Ex Parte Schulhauser,
No. 2013-007847, 2016 WL 6277792 (P.T.A.B. Apr. 28, 2016)..... 5, 9, 10-11

Summit 6, LLC v. Samsung Elecs. Co., Ltd.,
802 F.3d 1283 (Fed. Cir. 2015) 5

Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp.,
785 F.3d 625 (Fed. Cir. 2015) 19, 20

Vanda Pharm., Inc. v. Teva Pharm. USA, Inc.,
Case No. 18-651-CFC, 2022 WL 17593282 (D. Del. Dec. 13, 2022) .....*passim*

Vanda Pharm., Inc. v. Teva Pharm. USA, Inc.,
No. 2023-1247, 2023 WL 3335538 (Fed. Cir. May 10, 2023).....2

Vita-Mix Corp. v. Basic Holding, Inc.,
581 F.3d 1317 (Fed. Cir. 2009) 17

Rules

Fed. R. Civ. P. 12(c)..... 5-6, 7

Other Authorities

Charles A. Wright & Arthur R. Miller,
Federal Practice & Procedure(s) 1367 (2004) 6

I. INTRODUCTION

Defendants Apotex Inc. and Apotex Corp. ("Apotex") and Teva Pharmaceuticals USA, Inc. ("Teva") move for judgment on the pleadings that claims 1-3 of U.S. Patent No. 11,285,129 ("the '129 patent") are invalid as obvious based on collateral estoppel or, in the alternative, that claims 1-3 are not infringed.

II. NATURE AND STAGE OF THE PROCEEDINGS

A. The Pending Actions

Vanda filed these consolidated actions against Apotex and Teva in the District of New Jersey on December 27, 2022. D.I. 1. Two days later, Vanda moved for a temporary restraining order ("TRO") seeking to enjoin Defendants from launching their generic tasimelteon products. C.A. No. 23-153, D.I. 5; C.A. No. 23-152, D.I. 7. Defendants filed a cross-motion to transfer the case to this Court (C.A. No. 23-153, D.I. 18; C.A. No. 23-152, D.I. 23), which the New Jersey court granted (C.A. No. 23-153, D.I. 47; C.A. No. 23-152, D.I. 53). Vanda then withdrew its TRO motion. C.A. No. 23-153, D.I. 52; C.A. No. 23-152, D.I. 58.

Following an in-person status conference on May 9, 2023, Vanda filed its First Amended Complaint ("FAC") on May 12, 2023. C.A. No. 23-153, D.I. 86; C.A. No. 23-152, D.I. 94. The pleadings having closed, Apotex and Teva now seek entry of judgment in their favor under Rule 12(c).

B. The Prior Litigation Involving Related Patents

Vanda previously sued Apotex and Teva in this Court alleging infringement of fourteen other Orange Book-listed patents for Vanda's Hetlioz® product. *See* Case No. 18-651 (CFC) (consolidated) (the "Prior Litigation"). Among the patents asserted by Vanda were U.S. Patent Nos. RE46,604 ("the RE604 patent") and 10,149,829 ("the '829 patent"), which are related to the '129 patent and share a specification. Following a four-day bench trial, this Court found claim 3 of the RE604 patent and claim 14 of the '829 patent invalid as obvious. *Vanda Pharm., Inc. v. Teva Pharm. USA, Inc.*, Case No. 18-651-CFC, 2022 WL 17593282 (D. Del. Dec. 13, 2022). The Federal Circuit affirmed. *Vanda Pharms. Inc. v. Teva Pharm. USA, Inc.*, No. 2023-1247, 2023 WL 3335538 (Fed. Cir. May 10, 2023).[1]

Important here, this Court previously found (and the Federal Circuit affirmed) that methods of treating Non-24 (i.e., Non-24-Hour Sleep-Wake Disorder) by administering 20 mg of tasimelteon once daily about one-half hour to about one-and-one-half hours before a target bedtime are obvious over the prior art. *See* 2022 WL 17593282, *9-*10, *15-*17; 2023 WL 3335538, at *4.

III. SUMMARY OF THE ARGUMENT

The '129 patent's claimed methods of administering tasimelteon are invalid

[1] Vanda has filed a petition for rehearing, which is currently pending. As a result of that petition, the Federal Circuit's mandate has not yet issued.

for the same reasons that this Court previously found the claims of the related RE604 and '829 patent invalid in the Prior Litigation. The only difference between the claims of the '129 patent and those of the RE604 and '829 patents is a requirement to determine "whether a patient is being treated with a [beta-blocker]," which adds no patentable distinction to the claims at issue.

In the alternative, to the extent Vanda argues and the Court agrees that the asserted claims are not invalid under collateral-estoppel principles because they require discontinuing a beta-blocker and then administering tasimelteon, Defendants do not induce infringement of the '129 patent as a matter of law. Defendants' FDA-approved labels do not instruct physicians to discontinue treatment with a beta-blocker and then administer tasimelteon.

IV. THE ASSERTED '129 PATENT

The '129 patent claims purportedly improved methods of administering tasimelteon in which a physician first determines "whether the patient is being treated with a beta-adrenergic receptor antagonist" (i.e., a beta-blocker).

The three issued claims of the '129 recite the following:

> 1. In a method of administering tasimelteon to a patient, the improvement comprising:
>
> determining whether the patient is being treated with a beta-adrenergic receptor antagonist; and
>
> in the case that it is determined that the patient is not being treated with a beta-adrenergic receptor antagonist, administering to the patient 20 mg of tasimelteon once

> daily about one-half hour to about one-and-one-half hours before the target bedtime; or
>
> in the case that it is determined that the patient is being treated with a beta-adrenergic receptor antagonist;
>
> instructing the patient to cease treatment with the beta-adrenergic receptor antagonist; and then
>
> administering to the patient 20 mg of tasimelteon once daily about one-half hour to about one-and-one-half hours before the target bedtime.
>
> 2. The improvement of claim 1, wherein the beta-adrenergic receptor antagonist is selected from a group consisting of: alprenolol, altenolol, carvedilol, metoprolol, and propranolol.
>
> 3. The improvement of claim 2, wherein the patient is suffering from Non-24-Hour Sleep-Wake Disorder.

D.I. 86-1 at 36 (emphasis added).

Claim 1 of the '129 patent is very similar to claim 14 of the '829 patent that was at issue in the Prior Litigation, with one important distinction: while claim 14 of the '829 patent requires "discontinuing treatment with the strong CYP1A2 inhibitor" (2022 WL 17593282, *8), claim 1 of the '129 patent recites "instructing the patient to cease treatment with the [beta-blocker]" as only one of two possible options. Thus, claim 1 of the '129 patent is directed to a "conditional" method whereby a physician can take either of two courses of action:

> 1. If, on the one hand, the patient is not taking a beta-blocker, then tasimelteon is administered according to the prior-art method in which 20 mg of tasimelteon is administered once daily about one-half hour to about one-and-one-half hours before a target bedtime;

or,

> 2. If, on the other hand, it is determined that the patient is taking a beta-blocker, then the physician must instruct the patient to "cease treatment" with the beta-blocker, and then administer tasimelteon by the same prior-art method in which 20 mg of tasimelteon is administered once daily about one-half hour to about one-and-one-half hours before a target bedtime.

These two "conditional" steps are joined by "or," which means that, if the first step is practiced, the method ends and the second step is not reached. To show invalidity of this type of claim, it is necessary only to provide evidence that one of the optional limitations is found in the prior art. *See, e.g., Brown v. 3M*, 265 F.3d 1349, 1352-53 (Fed. Cir. 2001) (a claim written in the alternative is anticipated if any of the optional limitations is in the prior art); *Ex Parte Schulhauser*, No. 2013-007847, 2016 WL 6277792, *9 (P.T.A.B. Apr. 28, 2016) (same).

Further, no claim construction is required to reach the conclusion that "or," as that term is used in claim 1 of the '129 patent, does not mean "and," as such a term needs no construction when its "plain and ordinary meaning … is clear." *See, e.g., Summit 6, LLC v. Samsung Elecs. Co., Ltd.*, 802 F.3d 1283, 1291 (Fed. Cir. 2015). Claim construction should be similarly unnecessary for "determining," which—to the extent it is limiting—should have its plain and ordinary meaning.

V. RELEVANT LEGAL STANDARDS

A. Judgment on the Pleadings

Under Rule 12(c), the court should grant judgment on the pleadings if "no material issue of fact remains to be resolved and that the movant is entitled to

judgment as a matter of law." *Rodriguez v. Stevenson*, 243 F. Supp. 2d 58, 62 (D. Del. 2002). A Rule 12(c) motion is especially useful where, as here, "only questions of law remain to be decided by the district court." 5C Wright & Miller, *Federal Practice & Procedure* § 1367 (3d ed. 2023) (citations omitted). While factual allegations in the complaint are presumed true on a Rule 12(c) motion, legal conclusions are not entitled to any such presumption. *Id.*; *see Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

In evaluating a motion for judgment on the pleadings, a court may consider the pleadings, exhibits attached to the pleadings, matters of public record, and any documents "integral to or explicitly relied upon" in the pleadings. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997).

B. Invalidity Based on Collateral Estoppel

"[W]here a patent has been declared invalid in a proceeding in which the 'patentee has had a full and fair chance to litigate the validity of his patent,' … the patentee is collaterally estopped from relitigating the validity of the patent." *Miss. Chem. Corp. v. Swift Agric. Chems. Corp.*, 717 F.2d 1374, 1376 (Fed. Cir. 1983) (quoting *Blonder-Tongue Lab'ys, Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 333 (1971)). Collateral estoppel is not limited "to patent claims that are identical. Rather, it is the identity of the issues that were litigated that determines whether collateral estoppel should apply." *Ohio Willow Wood Co. v. Alps South, LLC*, 735

F.3d 1333, 1342 (Fed. Cir. 2013).

Collateral estoppel may bar re-litigation of common issues in actions involving different, but related, patents. *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 252 F.3d 1306, 1310 (Fed. Cir. 2001). Whether the difference between the patent claims materially alters the question of patentability is a legal conclusion based on underlying facts. *Google LLC v. Hammond Dev. Int'l, Inc*., 54 F.4th 1377, 1381 (Fed. Cir. 2022). The Supreme Court has endorsed Rule 12(c) motions for disposing patent cases through collateral estoppel. *Blonder-Tongue*, 402 U.S. at 348.

The Third Circuit has identified "four standard requirements for the application of collateral estoppel." *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d. Cir. 2006).[2] These are: (1) the identical issue was previously litigated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from re-litigating the issue was fully represented in the previous action. *Id*. (citations, quotations omitted). Once the four criteria are met, a court has no discretion to not apply collateral estoppel on equitable "considerations of justice and equity." *Biogen Int'l GMBH v. Amneal Pharm. LLC*, Case No. 17-823 (MN),

[2] The Federal Circuit applies the law of the regional circuit to issue-preclusion determinations. *Intellectual Ventures I LLC v. Capital One Fin. Corp*., 850 F.3d 1322, 1137 (Fed. Cir. 2017).

2020 WL 5549084, *8 (D. Del. Sept. 16, 2020).

VI. ARGUMENT

A. Vanda is Collaterally Estopped from Asserting The '129 Patent Against Defendants

Vanda is barred by the collateral estoppel effect of this Court's obviousness findings in the Prior Litigation from asserting the '129 patent against Defendants.

In the Prior Litigation, this Court held claim 3 of the RE604 patent and claim 14 of the '829 patent invalid as obvious. 2022 WL 17593282, *9-*10, *15-*17. The '129 patent at issue here is a continuation of the RE604 and '829 patents, which share a common specification with the '129 patent. *See* D.I. 86-1 at 1.[3] In finding the claims of the RE604 and '129 patents invalid as obvious, this Court found that methods of treating Non-24 by administering 20 mg of tasimelteon once daily about one-half hour to about one-and-one-half hours before a target bedtime were obvious in light of the prior art. *See* 2022 WL 17593282, *9-*10, *15-*17.

There can be no dispute that the obviousness of the related RE604 and '829 patents was actually litigated in the Prior Litigation, or that the validity of the RE604 and '829 patents was necessary to this Court's opinion and entry of final judgment. Nor can Vanda credibly dispute that it was fully represented as a party in that proceeding. Thus, the sole question is whether the issue of invalidity of the

[3] The RE604 patent is a Reissue of U.S. Patent No. 8,785,492, which is referenced on the face of the '129 patent.

claims of the '129 patent is "substantially identical" to that decided with respect to the RE604 and '829 patents in the Prior Litigation.

1. This Court Has Already Found the Operative Method Steps Claimed in the '129 Patent Obvious

Claim 1 of the '129 patent purports to be an "improvement" over prior-art methods of "administering tasimelteon to a patient." However, this Court found that the dose of tasimelteon (20 mg), the patient population (Non-24 patients, as recited in claim 3), and the timing of administration (once daily about 30 to about 90 minutes before a target bedtime) required by the claims of the '129 patent were all disclosed in the prior art. *Vanda*, 2022 WL 17593282, *9-*10, *15-*17. Thus, the only element of claim 1 of the '129 patent that distinguishes it from the claims of the RE604 and '829 patents that were found obvious is "determining whether the patient is being treated with [a beta-blocker]."

Importantly, because claim 1 of the '129 patent (and claims 2-3 that depend therefrom) uses the conditional transition phrase "or," that claim is invalid if either of the two optional methods is taught or suggested by the prior art. *Brown*, 265 F.3d at 1352-53; *Ex Parte Schulhauser*, 2016 WL 6277792 at *9.[4]

[4] Vanda alleges that "to prove invalidity of the '129 patent, both pathways" (1) and (2) noted above must be shown to be invalid. *See* C.A. No. 23-153, D.I. 86 at ¶ 67; C.A. No. 23-152, D.I. 94 at ¶ 66 (citing *Lincoln Nat'l Life Ins. Co. v. Transamerica Life Ins. Co.*, 609 F.3d 1364 (Fed. Cir. 2010)). Vanda is wrong. Because one need only perform one of the two pathways to practice the claim, one need only show that one of the two pathways is obvious to render it invalid. *See KSR Int'l Co. v.*

In *Brown*, the claim limitation at issue recited:

> a[t] least one database file stored in the memory containing records with year-date data with years being represented by at least one of two-digit, three-digit, **or** four-digit year-date representations; and
>
> a mechanism for converting the year-date data representations in the database file to a two-digit year-date data representation.

Brown, 265 F.3d at 1352. There, it was undisputed that the prior art taught the claimed two-digit representation but did not disclose the alternative three- or four-digit representations. *Id*. The claim was nonetheless found invalid as anticipated because it was "written in the alternative, and as written would be literally infringed by a system that offsets year dates in two-digit formats," and "[t]hat which infringes later anticipates if earlier." *Id*. at 1352-53.

Similarly, in *Ex Parte Schulhauser*, the claim at issue recited "comparing [an] electrocardiac signal data with a threshold electrocardiac criteria" and then either (1) "triggering an alarm state if the electrocardiac signal data is not within the threshold electrocardiac criteria" or (2) "determining the current activity level of the subject from the activity level data if the electrocardiac signal data is within the threshold electrocardiac criteria." 2016 WL 6277792 at *3. The PTAB held

---

Teleflex Inc., 550 U.S. 398, 419 (2007) ("If [a] claim extends to what is obvious, it is invalid under § 103."). *Lincoln*, moreover, does not support Vanda's position. That case addressed infringement, not invalidity, and in any event did not involve a claim reciting two conditional method steps joined by "or."

that the claim was not patentable because the prior art disclosed the first of the recited triggering steps and that no evidence of the obviousness of the remaining steps was required because those steps were optional. *See id*. at *3-*4.

The same result is appropriate here. Because Vanda wrote claim 1 of the '129 patent in the alternative using the "or" connector, if the first step is performed (based on the patient not being treated with a beta-blocker), then logically the second step need not be performed—and indeed could not be performed on the same patient. Therefore, as in *Brown* and *Schulhauser*, steps (1) and (2) of claim 1 of the '129 patent are mutually exclusive and only one of the recited steps need be performed to practice the patented method.

Further, the first of the two options here—administering 20 mg tasimelteon once daily about one-half hour to about one-and-one-half hours before bedtime—is precisely the method this Court (and the Federal Circuit) already found obvious. Specifically, while the wording of the claims of the '129 patent is not identical to those claims of the RE604 and '829 patents that were held invalid as obvious in the Prior Litigation, the issues are the same—specifically, whether administering 20 mg of tasimelteon to a Non-24 patient once daily 0.5 to 1.5 hours before a target bedtime was obvious. *See, e.g.*, *Ohio Willow Wood*, 735 F.3d at 1342 ("Our precedent does not limit collateral estoppel to patent claims that are identical. Rather, it is the identity of the *issues* that were litigated that determines whether

collateral estoppel should apply.").

Here, collateral estoppel applies because the only new element required by claims 1-3 of the '129 patent (i.e., the "determining" step) adds no patentable weight to an otherwise invalid method, and in any event is indisputably disclosed in the prior art. There is thus no factual basis for Vanda's assertion that the claims of the '129 patent are materially different and present materially different questions of invalidity from those of the RE604 and '829 patents that were heard in the Prior Litigations. *See* C.A. No. 23-152, D.I. 94 at ¶ 65; C.A. No. 23-153, D.I. 86 at ¶ 66.

a. The "determining" step should receive no patentable weight because it does not modify the prior-art method of administering tasimelteon.

Claims 1-3 of the '129 patent are invalid based on principles of collateral estoppel because the "determining" step does nothing to modify the prior art method of administering tasimelteon recited by the first conditional step of claim 1. Where a claim element does not modify a prior-art method of administering a drug, that element does not render the claim patentable. *See King Pharm., Inc. v. Eon Labs, Inc*., 616 F.3d 1267, 1278-79 (Fed. Cir. 2010).

In *King*, claims directed to methods of administering a drug (metaxalone) with food in order to increase bioavailability were found invalid on summary judgment because some of the claims merely required "informing" the patient of the increased bioavailability. *See id*. There, the relevant question was "whether the

additional instructional limitation … has a 'new and unobvious functional relationship' with the known method of administering metaxalone with food." *In re Kao*, 639 F.3d 1057, 1072 (Fed. Cir. 2011) (discussing *King*, quoting *In re Ngai*, 367 F.3d 1336, 1338 (Fed. Cir. 2004)). Further, in *King*, the accused patent infringer was not required to introduce evidence that the "informing" limitation was disclosed in the prior art because an otherwise invalid method does not become patentable by including such a "nonpatentable" limitation. *Id*. at 1278. *King* also analogized the "nonpatentable" method of "informing" to "printed matter" that does not functionally relate to the practice of a method that was otherwise disclosed in the prior art. *See id*. at 1278-79.

Similarly, in *Praxair Distr., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd.*, claim elements that required "determining that a neonatal patient has [a] preexisting" condition, and then "evaluating the potential benefit" of treatment with the claimed drug (inhaled nitric oxide) were found to lack patentable weight. 890 F.3d 1024, 1033 (Fed. Cir. 2018). These steps, the court held, were "no more than a 'think about it' step." *Id.*

Here, claim 1 of the '129 patent merely recites "determining" whether a patient is taking a beta-blocker and then administering tasimelteon by a method that was found invalid in the Prior Litigation. Contrary to Vanda's assertion, the determining step does not "modif[y] how the claim is practiced." C.A. No. 23-152,

D.I. 94 at ¶ 68; C.A. No. 23-153, D.I. 86 at ¶ 69. Rather, as in *King*, the determining step, as applied to the first conditional step of claim 1, instructs the physician to treat a Non-24 patient *not* taking a beta blocker in precisely the same way as this Court already found obvious in the Prior Litigation.[5] And, as in *Praxair*, the determining step can be viewed as no more than a requirement for a doctor to obtain information, "think about it," and then administer tasimelteon by a method that has already been found invalid.

Claim 2 is similarly invalid because, as applied to the first conditional step of claim 1, it merely recites a list of known beta-blockers that a patient is not taking. Claim 2 likewise receives no patentable weight because the limitations have no effect on the method recited in the first conditional step of claim 1. Finally, claim 3 recites that the patient has Non-24, which this Court found was explicitly disclosed in the prior art. *See* 2022 WL 17593282, *9-*10, *15-*17.

For these reasons, claims 1-3 should be found invalid based on collateral estoppel because the "determining" step required by claim 1 does not render patentable an otherwise invalid method of administering tasimelteon.

b. The "determining" step is indisputably not new

[5] Defendants do not concede that the second "conditional" step recited by claim 1 (i.e., discontinuing treatment with a beta-blocker and then administering tasimelteon) adds any patentable subject matter. But that question is not relevant here; because Vanda chose to draft claim 1 using conditional language, all that is required is that one of the conditional methods is found in the prior art.

Even if the "determining" step is a limitation of claim 1, that does not affect the obviousness analysis because this step is indisputably not new. On its face, this step merely requires a doctor to find out if a patient is taking a beta-blocker.

As anyone who has been to a doctor knows, every patient questionnaire asks what medications a patient is taking.[6] Indeed, Vanda's FAC itself alleges that "some, if not all, physicians would thoroughly check … if the patient is taking another medication." D.I. 86 at ¶ 51.[7] And certainly this was true before Vanda filed its patent applications. The '129 patent itself admits that beta-blockers "are known to reduce endogenous levels of melatonin." D.I. 86-1 at 21, col. 8:65 – col. 9:6. Given that this knowledge was admittedly in the prior art, there should be no dispute that it would be obvious to at least "determine" whether a patient to whom one intends to administer a melatonin agonist is currently taking a beta-blocker.

Further, in finding the asserted claims of the RE604 and '829 patents obvious, this Court relied on prior art that disclosed the use of tasimelteon in clinical trials to evaluate its use in a wide range of conditions, including the treatment of Non-24, insomnia, and the ability to phase-shift. *See* 2022 WL 17593282, *9-*10, *15-*17 (citing Lankford, Hardeland, the '244 publication, and Vanda's prior-art clinical trial protocol). Given the admittedly known interaction

[6] *See, e.g.*, http://www.charlydmiller.com/COMM/medquestions.html.
[7] As noted below, Defendants dispute that their respective labels contain any specific instructions to specifically ask whether a patient is taking a beta-blocker.

between melatonin agonist and beta blockers, it would have been self-evidently obvious to have determined whether the clinical-trial subjects were taking a beta blocker before administering tasimelteon.

As discussed above, claim 2 merely recites a list of beta-blockers that were known in the prior art, and claim 3 requires that the patient has Non-24. There is simply nothing new in these claims that makes them patentable over the claims of the RE604 and '829 patents that this Court previously found invalid.

Accordingly, claims 1-3 should be found invalid based on collateral estoppel because the "determining" step—even if it is a limitation of claim 1—adds nothing that makes these claims patentable over the prior art in the Prior Litigation.

B. In The Alternative, Defendants Are Entitled to Judgment on the Pleadings of Non-Infringement

Even if Vanda were correct that Defendants must show that both options recited in claim 1 are in the prior art to prove invalidity, Defendants would still be entitled to judgment on the pleadings, because such a construction would render it impossible for Vanda to prove infringement. Defendants' labels do not instruct patients to cease treatment with a beta-blocker and then take tasimelteon, as required by the second conditional method step of claim 1 of the '129 patent.

Defendants do not and will not directly infringe the '129 patent because, as pharmaceutical companies, they do not administer tasimelteon to patients. Vanda must therefore rely on a theory of induced infringement. To show inducement,

Vanda must show that Teva and Apotex "possessed specific intent to encourage another's infringement." *DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc). "The question is not … whether a user following the instructions may end up using the device in an infringing way. Rather, it is whether [the] instructions teach an infringing use of the device such that we are willing to infer from those instructions an affirmative intent to infringe the patent." *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 n.2 (Fed. Cir. 2009).

Vanda asserts that physicians reading the FDA-approved label for tasimelteon "would understand [it] to instruct the reader to avoid the use of beta-blockers." *E.g.*, C.A. No. 23-153, D.I. 86, ¶ 48; *see id.* ¶ 55. A closer look at the language in the label that Vanda's complaint cites proves otherwise. *Cf. BotM8 LLC v. Sony Corp. of Am.*, 4 F.4th 1342 (Fed. Cir. 2021) (affirming dismissal of patent-infringement claims where patentee's theory of infringement was contradicted by the complaint's factual allegations about the accused product). Apotex's and Teva's labels state only that "[b]eta-adrenergic receptor antagonists have been shown to reduce the production of melatonin via specific inhibition of beta-1 adrenergic receptors. Nighttime administration of beta-adrenergic receptor antagonists may reduce the efficacy of tasimelteon." C.A. No. 23-153, D.I. 5-9 at 5.[8] This language, on its face, does not direct anyone to stop using beta-blockers.

[8] This cite is to Apotex's label. The wording in Teva's label is identical.

In the Prior Litigation, the same Section 7 of Defendants' labels were at issue concerning whether Defendants induced infringement of the '829 patent by instructing physicians to discontinue administering a CYP1A2 inhibitor prior to administering tasimelteon. Trial Tr. (3/29/2022) 516:1 – 518:14 (Winkelman), Ex. 1. This Court heard testimony that instructions in Defendants' labels to "avoid" co-administration of tasimelteon with a CYP1A2 inhibitor did not instruct providers specifically to discontinue treatment with a CYP1A2 inhibitor before administering tasimelteon. Similarly here, a provider following the language in Defendants' labels could avoid a drug-drug interaction between a beta-blocker and tasimelteon by simply administering a beta-blocker during the day rather than at night, or by increasing the dose of tasimelteon to counteract any reduced efficacy. Thus, Defendants' labels permit "substantial non-infringing uses," which supports a finding of non-infringement. *See HZNP Meds. LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680, 702 (Fed. Cir. 2019) (affirming summary judgment of no inducement).

Vanda's FAC alleges that "at least some doctors would counsel some patients taking certain beta-blockers to cease their use of those beta-blockers when taking" Defendants' generic tasimelteon products. *E.g.*, C.A. No. 23-153, D.I. 86 at ¶ 56. However, even if this assertion is true, it is black-letter law that "[t]he mere existence of direct infringement by physicians, while necessary to find liability for induced infringement, is not sufficient." *Takeda Pharm. U.S.A., Inc. v. West-Ward*

Pharm. Corp., 785 F.3d 625, 631 (Fed. Cir. 2015). And "vague label language cannot be combined with speculation about how physicians may act to find inducement." *Id.* at 632; *HZNP*, 940 F.3d at 702 (evidence that "some users might infringe" is insufficient to show inducement; patentee must "establish that the proposed label instructs users to perform the patented method") (cleaned up).

Moreover, Vanda's own expert has already conceded in this case that beta-blockers are used for very serious conditions (including heart failure, anxiety, tremors, and heart attack). C.A. No. 23-153, D.I. 5-2; C.A. No. 23-152, D.I. 7-2 (Combs Dec.) ¶ 55. There are thus very legitimate reasons why a physician would not want to discontinue their use—a fact Vanda's infringement theory ignores.[9]

Simply put, prescribing physicians could faithfully follow the instructions on Defendants' label without discontinuing beta-blockers. Vanda thus cannot establish the specific intent required for actively inducing infringement. *See, e.g.*, *Takeda*,

[9] As part of the TRO submissions, Vanda's expert Dr. Combs suggested that a physician following Defendants' labels might discontinue a beta blocker before administering tasimelteon and prescribe verapamil in place of a beta-blocker—implying that verapamil would be co-administered with tasimelteon. C.A. No. 23-153, D.I. 5-2, ¶ 57. That assertion directly contradicts his sworn testimony to this Court. At trial in the Prior Litigation, Dr. Combs testified that Defendants' labels taught physicians to avoid co-administering tasimelteon with a strong CYP1A2 inhibitor, including verapamil. *See* Trial Tr. (3/28/2022) 233:3–234:11 (Combs), Ex. 2 (testifying that Teva's and Apotex's labels instruct to discontinue use of strong CYP1A2 inhibitors before beginning tasimelteon); *id.* 248:25–249:2 (testifying that verapamil is a strong CYP1A2 inhibitor covered the claim). Here—when Vanda needs a different opinion about whether a doctor would co-administer verapamil and tasimelteon—Dr. Combs takes the exact opposite position.

785 F.3d at 632-33 (finding no induced infringement where it was undisputed that label's language allowed for "a host of [non-infringing] alternatives" and plaintiff could not show "that physicians would forego these alternatives" and choose the infringing course of action); *HZNP*, 940 F.3d at 702 (finding no induced infringement where label's instructions "d[id] not require" practicing the claimed method, which "reflect[ed] that the product ha[d] substantial noninfringing uses," precluding a finding of specific intent to induce infringement).

C. The Court should dismiss this case with prejudice

This is Defendants' second Rule 12(c) motion. Rather than opposing the first, Vanda amended its complaint. But Vanda's amendments amounted to peppering its complaint with legal conclusions about infringement and about the differences between the '129 patent and the patents in the Prior Litigation—legal conclusions that, as explained above, are simply wrong. *Cf. Ashcroft*, 556 U.S. at 678 (complaint's legal conclusions are not presumed true). Vanda cannot cure the fatal flaws in its case. The Court should dismiss with prejudice. *See Burlington*, 114 F.3d at 1434 (dismissal with prejudice is appropriate if further amendment would be futile).

VII. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant their motion for judgment on the pleadings.

Dated: June 28, 2023

Respectfully submitted,

/s/ Nathan R. Hoeschen
John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
Nathan R. Hoeschen (No. 6232)
SHAW KELLER LLP
I.M. Pei Building
1105 N. Market Street, 12th Floor
Wilmington, DE 19801
Tel: (302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
nhoeschen@shawkeller.com

Of Counsel:

J.C. Rozendaal
Deirdre M. Wells
Byron L. Pickard
Will H. Milliken
William D. Rodenberg
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 New York Avenue, NW
Suite 600
Washington, DC 20005
Tel: (202) 371-2660

Counsel for Defendant and Counterclaim Plaintiff Teva Pharmaceuticals USA, Inc.

/s/ Kaan Ekiner
Kaan Ekiner (No. 5607)
COZEN O'CONNOR
1201 N. Market Street, Suite 1001
Wilmington, DE 19801
Tel: (302) 295-2046
kekiner@cozen.com

Of Counsel:

W. Blake Coblentz
Aaron S. Lukas
Kerry B. McTigue
COZEN O'CONNOR
1200 19th Street, NW
Washington, DC 20036
Tel: (202) 912-4800

Keri L. Schaubert
COZEN O'CONNOR
3 WTC, 175 Greenwich Street
55th Floor
New York, NY 10007
Tel: (212) 883-2258

Counsel for Defendants and Counterclaim Plaintiffs Apotex Inc. and Apotex Corp.

CERTIFICATE OF COMPLIANCE

In compliance with this Court's November 10, 2022 Standing Order Regarding Briefing in All Cases, Defendants certify that the foregoing Opening Brief In Support Of Their Motion For Judgment On The Pleadings is in Times New Roman 14-point font and includes a total 4,998 words excluding the cover page, Table of Contents, and Table of Authorities as determined using the word-count function in MS Word, and therefore complies with this Court's type, font, and word limitations.

/s/ Kaan Ekiner
Kaan Ekiner (No. 5607)
COZEN O'CONNOR
1201 N. Market Street, Suite 1001
Wilmington, DE 19801
Tel: (302) 295-2046
Email: kekiner@cozen.com